UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF ILLINOIS

IN RE: TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION	)	Case No. 14 C 1748
	)	MDL No. 2545
This document relates to all cases	)	Judge Matthew F. Kennelly

SUBMISSION OF ABBVIE INC. AND ABBOTT LABORATORIES
IN ADVANCE OF MAY 6, 2015 CASE MANAGEMENT CONFERENCE

Following up on the discussion of Plaintiff Fact Sheets ("PFS") at the conclusion of the April 21 Case Management Conference ("CMC"), Defendants AbbVie Inc. and Abbott Laboratories (collectively "AbbVie") submit this memorandum in advance of the Court's May 6, 2015 interim CMC. The memo: (1) provides an update regarding the status of Plaintiffs' production of completed PFSs in compliance with Amended Case Management Order No. 9 ("Amended CMO 9"), which requires most Plaintiffs to produce completed PFSs and associated documents by May 8, 2015;[1] (2) describes the impact of the problems that have emerged in complying with Amended CMO 9; and (3) sets out a proposal for addressing those problems. AbbVie's proposal was outlined to Plaintiffs' counsel just before the April 21 CMC and has been discussed in detail since. AbbVie remains hopeful the parties will have an agreed proposal for the Court's consideration at the May 6 interim CMC.

I. A Very Substantial Portion of the Bellwether Pool Has Not Complied With CMO Requirements For Timely Submission of Completed Plaintiff Fact Sheets.

The Court's original Case Management Order No. 9 ("CMO 9"), entered October 6, 2014, directed each Plaintiff in this MDL to complete and produce a verified PFS, to produce records requested by and relating to the PFS, and to execute authorizations sufficient to allow for the collection of additional medical and employment records. After it became apparent that the PFS production was lagging behind case filings, AbbVie moved on February 18, 2015 to amend CMO 9, and the parties agreed to a detailed amendment just prior to the February 20 CMC. On March 3, 2015 the Court entered the agreed Amended CMO 9, which: (A) directed each Plaintiff in this MDL with a case then pending to produce a completed PFS and accompanying documents by no later than May 8, 2015 (the "Section A Plaintiffs"); and (B) directed any

[1] This submission addresses Plaintiffs who have filed claims against AbbVie as the sole Defendant ("AbbVie-only"), as that is the pool from which the initial bellwether trials will be selected.

Plaintiff who thereafter filed a Complaint to provide those materials within 80 days after his case is filed in, or transferred to the MDL (the "Section B Plaintiffs"). Amended CMO 9, at V.A, B. Significantly, as negotiated by the parties and ordered by the Court, Amended CMO 9 imposed a special duty on any Plaintiffs asserting claims against AbbVie only, requiring those Plaintiffs to take "reasonable actions" to produce a PFS "at the earliest practicable date." Amended CMO 9, at V.C.

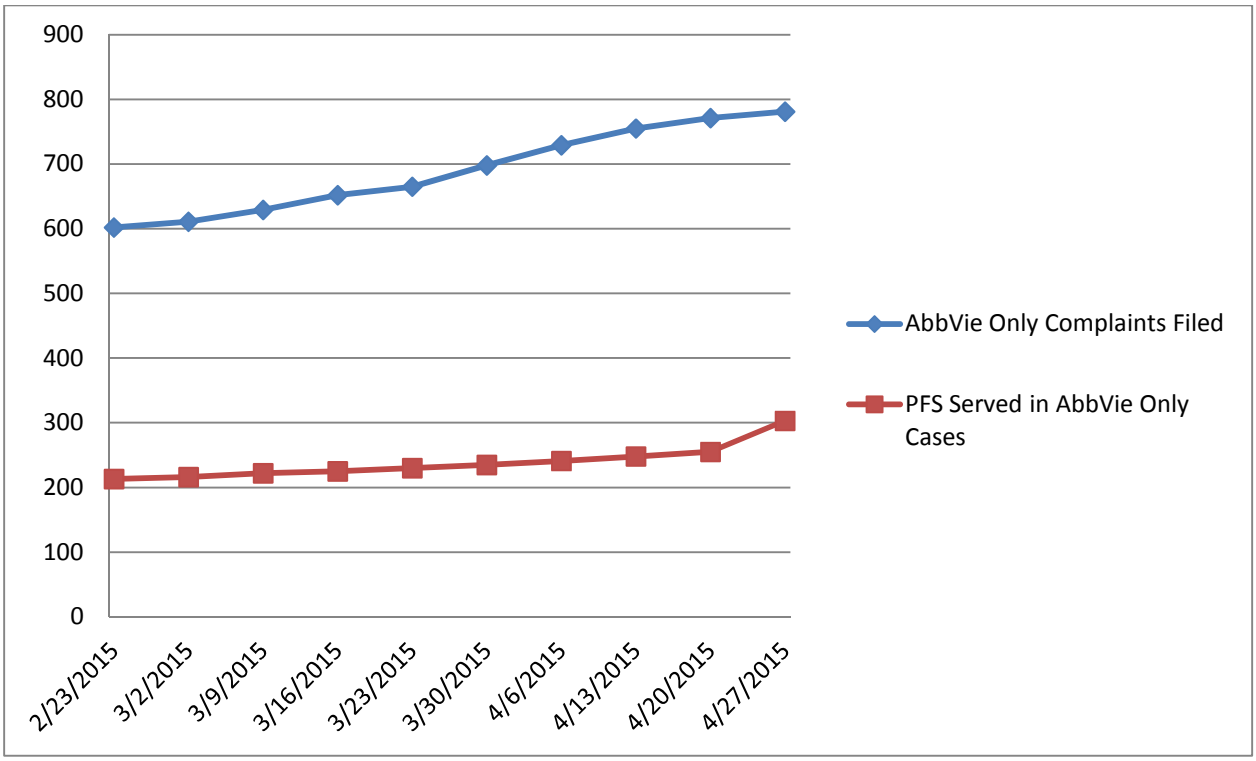
When negotiating this special duty, the Plaintiffs' Executive Committee ("PEC") was aware of the need for prompt production of PFSs and accompanying materials. In fact, the PEC confirmed in a contemporaneous "side letter" its understanding that AbbVie may seek modification of the bellwether schedule in Case Management Order No. 14 ("CMO 14") unless at least 90% of Section A Plaintiffs completed PFSs by May 8. As the PEC appreciates, the side letter, production targets, and Section V.C of Amended CMO 9 were all intended to assure that the parties could promptly collect as much information as possible about the characteristics of the pool as a whole—a goal that benefits AbbVie, Plaintiffs, and ultimately, the Court during the bellwether selection process.[2]

To date, most Plaintiffs have not met those obligations. As of May 1, there are 781 Plaintiffs in the MDL pursuing claims against only AbbVie. But only 303 of those Plaintiffs have produced a PFS, representing just 39% of the total pool. The circumstances surrounding this very low 'turnout' are particularly troublesome given the age of many of the claims. CMO 9 as amended carefully distinguished between claims already pending as of March 3 (when it was

[2] While, as the Court observed during the April 21 CMC, a side letter is not an order of the Court, the letter in this case reflected the agreement originally reached on AbbVie's motion to amend and was made a side letter at the Plaintiffs' request, for reasons concerning coordination with other plaintiffs' counsel. Indeed, the letter reflects that it is designed to be read as part of the agreed amended order. *See* March 2, 2015 e-mail correspondence (attached as Exhibit A).

entered) and claims filed thereafter. Many of the former, which totaled 608 as of March 3, had been pending for some time, and yet PFSs had been submitted for only 214 (or 35%) of them. Under Amended CMO 9, these "Section A" claimants were required to file PFSs by May 8 at the latest, a period of approximately 80 days. Yet, since March 3, only 83 (or 14%) additional PFSs have been submitted. No less than 311 additional Section A Plaintiffs must produce PFSs by Friday, May 8.

While AbbVie hopes and expects that more of these PFSs will come in by May 8, they are already untimely and materially so. These PFSs are extensive and, with the attached documents, the time to review them and begin to analyze them is substantial. Precisely for this reason, AbbVie pressed the PEC for an agreement that the PFSs would be produced "at the earliest practicable date," and this requirement (applicable to all AbbVie-only Plaintiffs) became part of the CMO. The trends are quite clear. While additional Plaintiffs continue to file Complaints at a steady pace, the pace of PFS completion and production has continued to lag far behind, even since AbbVie's February 18 motion, the Court's remarks on February 20 and the amendment of CMO 9 on March 3:



To make matters worse, AbbVie has already received *ad hoc* requests from some Plaintiffs' counsel asking for relief from the May 8 deadline. And it is already apparent that many of the late-produced PFSs will be incomplete and require individual follow-up, and potentially motion practice. As one example, a significant number of those who have filed AbbVie-only complaints have submitted PFSs acknowledging use of testosterone products manufactured by other Defendants, making the identification of the total universe of Plaintiffs in the AbbVie-only bellwether pool very much a moving target.

In all of this, AbbVie recognizes that the PEC does not control all of Plaintiffs' counsel. AbbVie itself has repeatedly offered to help reach out to other Plaintiffs' counsel with respect to the delays in PFS production, and the PEC has consistently counseled against this. AbbVie has deferred. Nor is AbbVie seeking to place blame on the PEC for the shortfalls. Rather, it simply

wants to get the process to work and on a basis that meets the goals of the pre-trial schedule. As set forth immediately below, those goals clearly are threatened.

II. Plaintiffs Must Provide Prompt, Complete, And Accurate Plaintiff Fact Sheets So The Parties Can Timely Propose, And The Court Can Order, An Effective Process For Selecting Bellwethers.

AbbVie remains committed to moving ahead in this litigation as quickly as possible. But PFS production delays to date have greatly prejudiced AbbVie's ability to collect and analyze the data and, in consequence, are compromising the first steps of the bellwether selection process.

In personal injury cases such as these, test cases (or "bellwethers") are an effective and important management tool. Both the case law and the published 'best practices' create clear requirements if these goals are to be achieved. The first is that the bellwethers must be representative of the claimant pool. Bellwethers are only effective if they represent the demographics, claims, and issues germane to the pool as a whole. As the Duke Law School Center for Judicial Studies cautions, "the bellwether process will be valuable only if the cases selected for trial are truly representative of the whole (or of more distinct categories of cases that comprise the whole) . . . . In the end, the key is to select cases that are representative of the entire claimant pool (or of specific categories in that pool)." *Standards and Best Practices for Large and Mass-Tort MDLs* 21-22, 27 (2014) ("*Standards and Best Practices*");[3] *see also* MANUAL FOR COMPLEX LITIGATION (FOURTH) § 22.315 (2004) ("The more representative the test cases, the more reliable the information about similar cases will be."). The Court is sensitive to this concern, having previously recognized the need to "maximize the likelihood that the bellwether

[3] *Available at* http://law.duke.edu/sites/default/files/centers/judicialstudies/standards_and_best_practices_for_large_and_mass-tort_mdls.pdf.

Duke developed the *Standards and Best Practices* after an "intensive two-year effort" involving a number of federal and state court judges, experienced plaintiffs' and defense practitioners, and scholars. *Id.* at i – vi.

selection and trial process will be both representative and productive." CMO 14 at 1. Indeed, absent a fair framework for selecting truly representative bellwether cases, the process typically devolves into competing lists of extremes, as the parties select the "best" and "worst" cases in the pool. *See generally In re Chevron, U.S.A., Inc.* 109 F.3d 1016, 1019 (5th Cir. 1997) (rejecting process that gave parties unfettered discretion to choose cases, because outcome was "not a bellwether trial," but "simply a trial of fifteen (15) of the 'best' and fifteen (15) of the 'worst' cases contained in the universe of claims involved in this litigation."). Invariably, many of those cases fall by the wayside before they can be fully litigated. This problem exists even where the Court permits the parties to "strike" a certain number of the adversary's selections; although the most extreme cases may be eliminated by strikes, several other non-representative "outlier" cases can remain in the bellwether pool. Of course, it is not possible to select bellwethers that are representative unless the pool from which those cases are selected is itself representative of the claimants in this MDL.

Second, the value of bellwethers depends upon obtaining detailed information about them. The process of selecting and working up bellwethers needs to provide the parties and the Court with a deeper understanding of the most central common issues, which helps drive the MDL to a just and efficient resolution. *In re Chevron*, 109 F.3d at 1019 ("The notion that the trial of some members of a large group of claimants may provide a basis for enhancing prospects of settlement or for resolving common issues or claims is a sound one that has achieved general acceptance by both bench and bar.").[4]

[4] For example, in the Meridia Products Liability Litigation, the MDL judge used pretrial motion practice to test the plaintiffs' scientific evidence and legal theories, ultimately excluding in part an expert's opinion and granting summary judgment as to the claims of all plaintiffs, in a decision that was affirmed by the Sixth Circuit Court of Appeals. *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791 (N.D. Ohio 2004), *aff'd sub nom. Meridia Prods. Liab. Litig. v.*

Third, the information used to select bellwethers must be equally available to both sides. Plaintiffs' counsel necessarily have a better understanding of the underlying facts of their clients' individual cases. In an attempt to level the playing field to the greatest extent possible given this natural advantage, however, the parties should operate with the same well-defined universe of information when making bellwether selections. *See Standards and Best Practices* at 30 (suggesting fact sheets and medical record authorizations allows for collection of "basic information about plaintiffs' claims," which facilitates "selection of more representative cases for trial," and "may aid the court in defining what constitutes a representative case and in identifying distinct categories of cases…"). It also prevents the parties from "gaming" the system and selecting "strong" or "weak" cases, not representative ones. *Id.* at 22, 30 ("The transferee judge must carefully consider how the bellwether selection process will work, and how to address cases that drop out of the pool, in order to minimize strategic behavior and enhance the value of the bellwether process . . . . The transferee judge should adopt rules that will minimize the risk that parties will attempt to 'game' the bellwether trial-selection process, resulting in test trials of cases that are not representative of the case pool as a whole.").

All of these requirements are reflected in the Court's CMOs in this case, but all are threatened by the failure to comply with the PFS provisions of Amended CMO 9—as the Court observed in February, failure to complete the PFSs can have a domino effect on the overall MDL schedule. Tr. of Feb. 20, 2015 Hearing, at 8-9 ("[T]he whole thing goes awry."). Thus:

Abbott Labs., 447 F.3d 861 (6th Cir. 2006). Similarly, in the Seroquel Products Liability Litigation, the MDL Court used *Daubert* and summary judgment motion practice to identify the significant holes in the plaintiffs' scientific evidence, ultimately excluding plaintiffs' causation experts and granting summary judgment in the first bellwether cases selected for trial. *Guinn v. AstraZeneca Pharm. LP*, 598 F. Supp. 2d 1239 (M.D. Fla. 2009); *Haller v. AstraZeneca Pharm. LP*, 598 F. Supp. 2d 1271 (M.D. Fla. 2009). Again, the Court of Appeals affirmed the MDL Court's pretrial rulings. *Guinn v. AstraZeneca Pharm. LP*, 602 F.3d 1245 (11th Cir. 2010). The litigation settled shortly thereafter.

(1) Today, the Section A Plaintiffs are representative only of those claimants who were early filers.

(2) AbbVie lacks completed PFSs even for most of the Section A Plaintiffs, and it has no or sparse documentation for many that have been completed.[5] The production of medical records is even further behind. To date, the parties have complete medical records for ***no*** Plaintiffs. This has occurred because of a confluence of factors, including the delay in getting PFSs and authorizations, and delays reaching certain discovery agreements and getting compliance from some Plaintiffs' counsel, notwithstanding the efforts of the PEC. The record collection process itself is also labor-intensive and time-consuming—it takes approximately 90 days from authorization just to collect the records. It is a virtual certainty that the parties would not be able to collect complete medical records for a meaningful sample of Plaintiffs until late summer or early fall, leaving only days to review and evaluate those records before selecting cases for inclusion in a representative bellwether pool.

(3) Until the PFSs are completed and the attachments are provided and reviewed, Plaintiffs have far more information at their disposal than does AbbVie.

The most immediate impact of the foregoing will be felt in connection with the proposal of the bellwether selection process currently set for July. Consistent with best practices, *Standards and Best Practices* at 20-32, the Court has ordered that the bellwether selection process be proposed by the parties but ultimately set by the Court. Proposals are due on July 11, with the Court to rule by July 31. By collecting data through the PFSs and accompanying documents, rather than launching into full-blown, inefficient discovery in every case, the parties should be able to identify the meaningful legal and factual criteria, and then group cases

[5] 69 of the PFSs completed to date attached less than 100 pages of supporting documents. 18 PFSs attached no supporting documents.

accordingly. The Court could then set a process for the actual selection to occur later in the year. Without the necessary data, this cannot be achieved.

III. The Parties Have Been Discussing Potential Solutions To The Challenges Posed By The Current Schedule.

Anticipating that the problems created by the delayed PFS production process will only grow and become more challenging with time if not addressed now, AbbVie has proactively engaged in a dialogue with the PEC to consider how the Court's schedule can be maintained while at the same time ensuring that the bellwether selection process will be rigorous, informed, meaningful, and fair. AbbVie proposes the following:

1) AbbVie would be agreeable to the Court allowing Section A Plaintiffs an additional 21 days, to May 29, 2015, to produce PFSs and the accompanying documents in AbbVie-only cases.

2) AbbVie would be agreeable to the Court allowing Section B Plaintiffs 120 days from the date of filing/transfer to produce PFSs and accompanying documents in AbbVie-only cases.

3) In exchange for agreeing to these extensions, and assuming the Section A Plaintiffs comply with the PFS production deadline, AbbVie believes the initial bellwether pool should be limited to Plaintiffs who have provided a completed PFS, the documents requested by the PFS, and medical authorizations by May 29, 2015.

4) AbbVie would support the Court modifying CMO 14, such that instead of the parties submitting their bellwether selection proposal by July 11, 2015, there would be a 30-day extension, to August 10, 2015. This interim deadline extension would not disturb the date by which the parties will identify the initial bellwether Plaintiffs (October 31, 2015).

5) To avoid the prospect of future delays due to the parties not being able to timely collect and review medical records in all Section A cases before bellwether selection, and to allow the parties to focus resources on other discovery obligations essential to preparing these

cases for summary disposition or trial, AbbVie believes the parties can and should select bellwether cases based solely on the information contained in the PFSs and related documents, and defer collecting records until after the parties have identified the first 32 cases that are selected for inclusion in the initial bellwether pool. *See Standards and Best Practices* at 8 (reporting that many of the judges surveyed "preferred to hold off on individual discovery until a pool of cases had been selected to act as bellwethers," because "individual discovery . . . could become a morass or black hole.").

While this approach would plainly conserve substantial party financial and time resources, and make practical sense, AbbVie recognizes that starting record collection in October would likely add 75-90 days to the current schedule for discovery that is scheduled to begin on October 31, 2015, assuming no unforeseen complications require additional scheduling modifications. Only after that review would the parties be in a position to take the other discovery provided for in CMO 14 and thereafter choose the first trial cases. While AbbVie is reluctant to propose any extension of current deadlines, it believes that fairness and efficiency considerations support modifying the plan as suggested. AbbVie also remains concerned that even if we maintain the current schedule and plan, it will become apparent in September or October that the schedule requires modification notwithstanding the best efforts of the parties, by which time there will already have been a significant diversion of resources to the record collection and review process.

Dated: May 4, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Christopher R. Boisvert, hereby certify that on May 4, 2015, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

/s/ Christopher R. Boisvert